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HFL-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M2428n

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-39

February 25, 1999

German A. Monsalve
President, InterExpress Corporation
7225 N.W. 25th Street, Suite 310
Miami, Florida 33122

Dear Mr. Monsalve:

On November 2, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 7225 N.W. 25th Street, Suite 310, Miami, Florida 33122. The investigator, Carlos W. Hernandez, documented for the second consecutive time this year, serious deviations from the seafood importing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of these deviations cause the fish products being imported and stored by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

> Your firm has failed to have and implement written verification procedures to insure that the aquaculture raised trout and other seafood products were processed in accordance with the requirements of the Seafood HACCP Regulation [21 CFR § 123.12(a)(2)];
>
> Your firm has failed to adequately perform the affirmative step in 21 CFR § 123.12(a)(2)(ii)(D) by not maintaining a copy of the foreign processor's HACCP plan in English for aquacultured trout from [redacted], or fresh smelt from [redacted], and you did not have a written guarantee from the foreign processors that the imported fish or fishery product is processed in accordance with the requirements of this part.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

Your should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice including seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, 6601 N.W. 25th Street (P.O. Box 59-2256), Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District